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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,526	11/28/2003	Robert E. Arbogast	OHI 1717-006	8908

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STANDLEY LAW GROUP LLP
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EXAMINER

KASENGE, CHARLES R

ART UNIT	PAPER NUMBER
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2125

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,526	ARBOGAST ET AL.	
	Examiner	Art Unit	
	Charles R. Kasenge	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-211 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-211 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/6/04, 8/1/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-20, 22-41, 43-66, 68-91, 110-142, 145-152, 163-184, and 186-210 are rejected under 35 U.S.C. 102(b) as being anticipated by Schall et al. U.S. Patent 5,824,111. Regarding claims 1, 22, 43, 48, 68, 73, 110, 129, 145, 153, 163-165, 186, 187, 192 and 193, Schall discloses a system for producing a custom prosthetic liner, comprising: a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb (col. 2, lines 52-54); a processing device for generating a 3-dimensional electronic liner model using said 3-dimensional shape captured by said shape capture apparatus, said processing device optionally adapted to generate a 3-dimensional electronic residual limb model (col. 3, lines 8-25); a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner (col. 8, lines 8-52); an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both (col. 3, lines 46-61); and a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component (col. 3, lines 46-61).

Regarding claims 2-4, 23-25, 44, 45, 49, 69, 70, 74, 94, 95, 98, 112, 115, 116, 131, 132,

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134, 137, 138, 160, 168, 169, 189-191 and 195, Schall implicitly discloses the system of claim 1, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors (col. 2, lines 52-54). Schall discloses the system of claim 1, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA) (col. 4, lines 35-41). Schall discloses the system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner (col. 3, lines 8-25).

Regarding claims 5-8, 26-29, 46, 47, 50-54, 71, 72, 78, 79, 96, 97, 99, 113, 114, 117, 118, 135, 136, 139, 140, 162, 170-173 and 196-199, Schall discloses the system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is remotely transmitted to said facility equipped to produce said custom liner (col. 8, lines 52-67). Schall discloses the system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN) (col. 8, lines 52-67). Schall discloses the system of claim 1, wherein said at least one custom mold component is produced from said data by a computer-controlled machining device (col. 3, lines 26-33). Schall discloses the system of claim 1, wherein said at least one custom mold component is created from a closed-cell foam material (col. 5, lines 25-29).

Regarding claims 9-15, 30-36, 55-61, 80-86, 100-102, 108, 109, 119, 120, 127, 128, 133,

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141, 142, 151, 152, 157, 158, 167, 174-179 and 200-205, Schall discloses the system of claim 1, wherein said at least one custom mold component is a mold core for use with a common mold cavity (col. 5, lines 21-28). Schall discloses the system of claim 9, wherein said mold cavity is selected based on its size (col. 5, lines 15-28). Schall discloses the system of claim 1, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core (col. 5, lines 15-28). Schall discloses the system of claim 1, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material (col. 5, lines 25-29). Schall discloses the system of claim 12, wherein said custom prosthetic liner is manufactured from a block copolymer material (col. 5, lines 38-50). Schall implicitly discloses the system of claim 1, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process (col. 7, lines 48-60). Schall discloses the system of claim 1, further comprising the ability to modify the shape of either or both of said 3-dimensional electronic models to accommodate particular features of said residual limb in said custom prosthetic liner (col. 4 and 5, lines 64-67 and 1-8).

Regarding claims 16-20, 37-41, 62-66, 87-91, 103-107, 122-126, 146-150, 154-156, 159, 180-184 and 206-210, Schall discloses the system of claim 1, further comprising the ability to select liner materials and material properties (col. 5, lines 25-29). Schall discloses the system of claim 1, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner (col. 4, lines 41-56). Schall discloses the system of claim 17, wherein the number, location, and orientation of said accessories may be specified (col. 4, lines 41-56). Schall discloses the system of claim 17, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders),

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additives, and sensors (col. 4, lines 41-56). Schall discloses the system of claim 18, wherein said additives include anti-microbial substances (col. 5, lines 25-29).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 21, 42, 67, 92-109, 143, 144, 153-162, 185 and 211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schall as applied to the claims above, and further in view of Onyshkevych et al. U.S. Patent 6,665,577. Schall does not disclose an automated system for configuring and purchasing a medical device (col. 8, lines 52-67). Onyshkevych, however, does disclose an automated system for configuring and purchasing a medical device (col. 2, lines 37-53 and col. 22, lines 49-50).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use an automated system to purchase a manufactured medical device. One of ordinary skill in the art would have been motivated to do this since Onyshkevych discloses customizing prosthetics for customers (col. 1, lines 15-18) and allowing for a transaction to take place (col. 2, lines 37-53 and col. 22, lines 49-50).

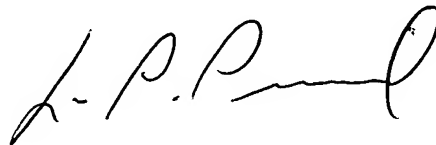
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles R. Kasenge whose telephone number is 571 272-3743. The examiner can normally be reached on Monday through Friday, 8:30 - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Picard can be reached on 571 272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CK
November 23, 2005



LEO PICARD
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